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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,975	01/10/2002	John Jairo Damarati	10121/02101	3029

7590

02/19/2004

Fay Kaplun & Marcin, LLP  
17th Floor  
100 Maiden Lane  
New York, NY 10038

EXAMINER
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ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/19/2004

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/045,975

Applicant(s)

DAMARATI, JOHN JAIRO

Examiner

Paul A Roberts

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 9, & 11 is/are rejected.
- 7) ☒ Claim(s) 3, 7, 8, 10 and 12-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 1941 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 4-6, 9, & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storz-Irion "Storz" et al. WO 01/80746 A1 in view of Thompson 5,662,654. Storz discloses a suturing tool comprising: (from figure 1) a first catheter (1) capable of being sealed into the working channel of an endoscope, a plurality of anchoring members (6), a driving member (7) extending through the first catheter (1) to a proximal end thereof, wherein advancing the driving member distally in the first catheter advances the anchoring members distally through the first catheter to drive a distal-most one of the anchoring member out of the first catheter, and a length of suture extending between the suture receiving proximal ends of the anchor members (this occurs once the anchors are placed in the body). As figure 1 shows, the circular anchors do not resemble the anchors of the applicant's invention. However, page 7, lines 22-27 states that the anchor member can be any suitable body, which fix-position the thread in an opening in a locking or positive manner. Thompson discloses a suturing device having anchoring members including a shaft extending from the tissue penetrating distal tip to the suture receiving proximal end and a gripping arm (figure 25, 141) having a gripping and insertion configuration. This anchor is superior to that of Storz because this anchor provides an enhanced anchoring means,

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the barbs, which act to prevent the anchor from being removed. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the anchors of the Storz device with the anchors of the Thompson device because the barbs of Thompson provide an enhanced anchoring means (141).

2. Regarding claim 2, the driving member of Storz is designed to press an anchor into a tissue. The composition of the material of the driving member is not disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the Storz driving member of metal since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. The driving member contains a piston. Since the piston could obviously be made of metal, and metal materials are inherently flexible, the piston is inherently flexible.

3. Regarding claim 4, the anchors shown in Storz appear to be floating on top of one another. Some force must exist to push the anchors into the lower triangle. This force is not disclosed. It would have been logical to use gravity to push the anchors towards the lower triangle to prepare the anchors to be inserted into the skin. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the force of gravity to pull the anchors towards the bottom of the catheter so they can be inserted into the skin. Since the combined device uses gravity to position the anchors, the anchors would be inherently be pressed next to one another by the force of gravity.

4. Regarding claim 5, the suture would be fixed to the distal most one of the anchoring members that are inserted.

5. Regarding claim 6, the barbs of the Thompson device (disclosed by Li) are made of nitinol. This material (the contact pressure mechanism) would release the gripping arm from the insertion configuration upon penetration of the tissue of the distal tip of the corresponding anchoring member.

6. Regarding claim 9, the outer casing of the Storz device (1) is considered the first catheter. The second catheter is element 8, which is inside the first catheter.

7. Regarding claim 11, element 10 is part of the driving mechanism, element 10 is a knot holding section. Element 16 is a suture cutting surface.

***Allowable Subject Matter***

Claims 3, 7, 8, 10, and 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 3, the combined Storz device doesn't disclose a catheter sized to maintain the anchor in the insertion configuration.

Regarding claims 7 and 8, multiple hinges on the catheters are not disclosed by Storz.

Regarding claim 10, the driving mechanism is inside a different catheter than the anchors.

Regarding claim 12, the driving member doesn't have a lumen with a suture within it.

Regarding claim 13, after the distal most anchor is deployed, the second catheter cannot couple with that anchor.

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Regarding claim 14, Storz does not disclose a suture holding pin in combination with claim 11.

Claims 15-17 are allowed. The following is a statement of reasons for the indication of allowable subject matter: claims 15-17, the Storz device doesn't disclose 3 concentric catheters interalia the limitations of claim 15.

### ***Response to Arguments***

Applicant's arguments, see pages 8 and 9, filed 1/15/04, with respect to the rejection(s) of claim(s) 121 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Storz-Irion "Storz" et al. WO 01/80746 A1 in view of Thompson 5,662,654.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Li 5207679 a suture anchor pusher.

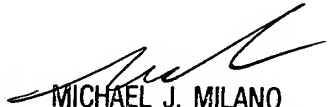
Knodel 6447524 a clip applier.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts  
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13/02/04

  
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